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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/830,195
Filing Date: April 22, 2004
Appellant(s): BUISER ET AL.

Sean P. Daley
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/20/2010 appealing from the Office action mailed 6/02/2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 are pending and rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

US 6,530,934	JACOBSEN	03-2003
US 2002/0177855	GREENE	11-2002
US 2003/0185895	LANPHERE	10-2003
US 7,131,997	BOURNE	11-2006
US 7,449,236	LANPHERE	11-2008
US 7,462,366	LANPHERE	12-2008
US 7,588,780	BUISER	09-2009
US 7,611,542	BOURNE	11-2009

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen *et al.* (US 6,530,934) and Greene (US 2002/0177855) in view of Lanphere *et al.* (US 2003/0185895).

Jacobsen discloses an embolic device comprised of a linear sequence of flexibly interconnected miniature beads. The device generally comprises a flexible elongated filament having a linear sequence of beads disposed thereon. The beads may be fixedly connected to the filament. The string of beads may be configured to the exact

length needed. The beads may be porous (abstract). The embolic device is used to occlude blood flow and/or initiate blood clotting upon introduction to the body via a catheter (column 1, lines 14 – 25). The string of beads includes a filament (i.e. a link) and beads. The beads have diameters from 0.002 inches to 0.0018 inches, and may be made of a variety of materials, including polymers, radioopaque polymers, metals. The beads may be integrally formed of the material of the filament (column 4, line 24). The string of beads may be comprised of beads of several different materials (column 4, lines 25 – 40). The filament can be a multi or monofilament polymer (column 5, line 21). The string of beads may be configured as a drug delivery device, wherein the beads are porous and contain a medicament for controlled release into the interior of the body (column 2, lines 44 – 47).

Greene discloses an embolization device for occluding a body cavity which includes one or more elongated hydrophilic embolizing elements non-releasably carried along the length of an elongated filamentous carrier (abstract). The embolizing agents (micropellets) may be made of a macroporous polymeric material or a porous, environmentally-sensitive, expansile hydrogel (abstract and paragraphs 0085 – 0088). The carrier (i.e. link) is preferably a nickel/titanium wire, but may also be formed from a polymer (paragraph 0093). The carrier has a diameter of approximately 0.04 mm (i.e. 0.0015 inches) (paragraph 0092). The length of the carrier is variable depending on the size of the vascular site to be embolized (paragraph 0085). See also Figure 1. The device may be contained in saline solution (paragraph 0029). The devices may be used to deliver therapeutic agents (paragraph 0141).

Jacobsen and Greene do not specifically recite that the porous beads have the pore size distribution as claimed.

Lanphere discloses a drug delivery device which is a substantially spherical polymer particle having an internal reservoir region including relatively large pores and a metering region substantially surrounding the reservoir region having fewer relatively large pores (paragraph 0004). A sustained, controlled-dosage release of a therapeutic agent can be achieved using the particles (paragraph 0010). The particles have a diameter in the range of 1 cm or less, e.g., 5 mm to 1 mm or less, e.g., about 1200 microns or less, and about 10 microns or more, e.g. about 400 microns or more and the pores are about 50 or 35 to 0.01 micron. Preferably, the particles are classified in size ranges of about 500-700 microns, about 700-900 microns, or about 900-1200 microns. The particles have a mean diameter in approximately the middle of the range and variance of about 20% or less, e.g. 15% or 10% or less (paragraph 0025). The particles can be considered to include a center region, C, from the center of the particle to a radius of about r/3, a body region, B, from about r/3 to about 2 r/3 and a surface region, S, from 2r/3 to r. The regions can be characterized by the relative size of the pores and the number of pores of given sizes. In embodiments, the center region has a greater number of relatively large pores than the body region and the surface region. The large pores are in the range of about 20 micron or more, e.g. 30 micron or more, or in the range of about 20 to 35 micron. The body region has a greater number of intermediate size pores than the surface region. The intermediate size pores are in the range of about 5 to 18 micron. In embodiments, the regions may also have different densities,

with the density of the surface region being greater than the density of the body region, and the density of the body region being greater than the density of the center region. The size of the pores in each of the regions can also be characterized by a distribution. In embodiments, the predominant pore size(s) in the center region being greater than the predominant pore size(s) in the body region and the predominant pore size(s) in the body region is greater than the predominant pore size(s) in the surface region. In embodiments, in the predominant pore size in the center region is 20 micron or more, e.g. 30 microns or more, or in the range of about 20 to 35 microns. The predominant pore size in the body region is about 18 micron or less, e.g. about 15 micron or less, or in the range of about 18 to 2 micron. The pores in the surface region are preferably predominantly less than about 1 micron, e.g. about 0.1 to 0.01 micron (paragraph 0026-0027). The particles can be used in chemoembolization (paragraph 0066). The particles are suspended in a carrier fluid, which may include saline and a contrast solution (paragraph 0030). The particles are preferably PVA (paragraph 0021).

Lanphere fails to recite that at least two particles are connected.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize the porous particles having a pore size distribution as disclosed by Lanphere as the porous beads in the embolic device comprised of a linear sequence of flexibly interconnected miniature beads, taught by Jacobsen, or the embolic micropellets positioned along the length of a carrier, taught by Greene, because the embolic devices of Jacobsen or Greene and the particles of Lanphere are used for controlled release drug delivery (see Jacobsen column 2, lines 44 – 47). One would

have been motivated to do so because Lanphere specifically teaches that a polymeric particle having an internal reservoir region including relatively large pores and a metering region having fewer relatively large pores controls the release of an agent from the particle, and are particularly useful for delivery of desired drug dosages for an extended period of time (see Lanphere paragraphs 0003 – 0010). It would have been further obvious to one of ordinary skill in the art at the time of the instant invention to apply the porous PVA particles taught by Lanphere in an interconnected form, as taught in the device of Jacobsen, because both the porous particles of Lanphere and the interconnected porous beads of Jacobsen are used for embolization. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because Jacobsen specifically teaches that hydrophilic particles which are used for occluding blood flow tend to become dislodged from the target site and migrate within the body potentially causing trauma or unwanted thrombosis, and that providing a device comprising a linear sequence of interconnected miniature beads is superior to individual particles because the device is less susceptible to migration within the body (column 1 – 2). Regarding claims 3 and 4, Jacobsen teaches that the carriers may be any desired length, and thus it would have been obvious to one of ordinary skill in the art to selectively prepare links within the claimed ranges. Regarding the limitations of link aspect ratio, ratio, length, it is noted that Jacobsen teaches that the carriers may be any desired length, and thus it would have been obvious to one of ordinary skill in the art to selectively prepare links within the claimed ranges, which would be directly related to aspect ratio within the extremely broad ranges based on the diameter of the

particles as a ratio to any length available. Greene and Jacobsen both teach that length of chain/filament, etc. may be selected by the user. See also Figures of Jacobsen, for example such as Figure 4. The width of the length is approximately 0.1 cm, and the length shown is approximately 5.5 cm. Such a width/length ratio shown would be within the widely varying claimed range of aspect ratio, especially since Jacobsen teaches that any length may be selected.

Double Patenting

Claims 1-4, 11, 23-31, 49-53,60, 62 and 63 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 7,131,997; 7,449,236; 7,462,366; 7,588,780 and 7,611,542 in view of in view of Jacobsen *et al.* (US 6,530,934) and Greene (US 2002/0177855).

Claims 1-4, 11, 23-31, 49-53, 60, 62 and 63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Application Serial No. 12/235,978, 12/236,051 and 10/651,475 in view of Jacobsen *et al.* (US 6,530,934) and Greene (US 2002/0177855).

The claims of the 7,131,997; 7,449,236; 7,462,366; 7,588,780 and 7,611,542 patents and the 12/235,978, 12/236,051 and 10/651,475 applications are drawn to polymeric particles having the pore size distribution overlapping in scope with that which is now claimed. While the embolic/therapeutic particles of the 7,131,997; 7,449,236;

7,462,366; 7,588,780 and 7,611,542 patents and the 12/235,978, 12/236,051 and 10/651,475 applications do not specifically recite that the particles are present on a particle chain comprising at least two connected particles and a link that connects the at least two connected particles, it is well known in the art to provide porous particles on a chain for embolization, as shown by Jacobsen and Greene. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because Jacobsen specifically teaches that hydrophilic particles which are used for occluding blood flow tend to become dislodged from the target site and migrate within the body potentially causing trauma or unwanted thrombosis, and that providing a device comprising a linear sequence of interconnected miniature beads is superior to individual particles because the device is less susceptible to migration within the body (column 1 – 2). Regarding chain length, Jacobsen and Greene teach that the carriers may be any desired length, and thus it would have been obvious to one of ordinary skill in the art to selectively prepare links within the claimed ranges. Regarding link width, Greene teaches the claimed width. Regarding the limitations of link aspect ratio, ratio, length, it is noted that Jacobsen teaches that the carriers may be any desired length, and thus it would have been obvious to one of ordinary skill in the art to selectively prepare links within the claimed ranges, which would be directly related to aspect ratio within the extremely broad ranges based on the diameter of the particles as a ratio to any length available. Greene and Jacobsen both teach that length of chain/filament, etc. may be selected by the user. See also Figures of Jacobsen, for example such as Figure 4. The width of the length is approximately 0.1 cm, and the length shown is

approximately 5.5 cm. Such a width/length ratio shown would be within the widely varying claimed range of aspect ratio, especially since Jacobsen teaches that any length may be selected. Accordingly, the claims are overlapping in scope and are obvious variants of one another.

(10) Response to Argument

Appellant argues on pages 2-4 of the Appeal Brief that the Examiner has failed to demonstrate how the references could have been combined, and that the obviousness rejection is improper because the Examiner has not demonstrated that the asserted combination of Jacobsen, Greene, and Lanphere would have enabled one skilled in the art to make the subject matter covered by the claims. Appellant asserts that neither Jacobsen nor Lanphere even disclose a process for joining particles, and therefore it cannot be properly asserted that Jacobsen and/or Lanphere enable Appellant's claimed subject matter. Appellant argues that the mere fact that Jacobsen discloses that, for the particular material he discloses, links and particles could be of the same material, does not change the conclusion where Appellant's claims cover different particles and links and Jacobsen is silent regarding the manner in which he allegedly made his disclosed subject matter. Appellant further recites that the processes disclosed by Greene would not work for Appellant's claimed subject matter, at least because the claimed subject matter requires the link and at least one of the particles to be integrally formed of the same material. Appellant argues that as a result, none of the references relied upon by

the examiner, alone or in the Examiner's proposed combination, enable one skilled in the art to make the subject matter covered by Appellant's claims.

This is not found to be persuasive. Jacobsen specifically teaches that the beads may be integrally formed of the material of the filament (column 4, line 24), and teaches polymer as a suitable material of both bead and filament, and also teaches porous particles. See also claim 25 of Jacobsen. Greene teaches that both the carrier and the micropellets may be made of PVA (see paragraphs 0093 and 0088). With regard to Applicant's argument that Jacobsen does not teach a process for joining particles, it is noted that a US patent is presumed to be operable/enabling per MPEP 2121. When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse,* 629 F.2d 675, 207 USPQ 107 (CCPA 1980). In addition, under 35 U.S.C. 282 a patent shall be presumed valid (i.e. and thus is presumed to meet the enablement requirement). The Jacobsen patent discloses and claims that filament and bead are integrally formed. The instant claims include the limitation that the particles and link are integrally formed. Absent evidence to the contrary, it is presumed that one of ordinary skill would have been able to provide integrally formed polymeric (porous) particles/beads on a polymeric filament, as disclosed and claimed by Jacobsen using polymer bead and filament; especially since Greene teaches similar porous micropellets affixed to a carrier, including use of PVA as both micropellet and carrier. It is noted that the instant claims are product claims, not method of making claims.

Appellant further argues on page 5 of the Appeal Brief for reconsideration of the obviousness-type double patenting rejections in view of the arguments presented in the preceding section.

This is not found to be persuasive, for reasons set forth above with regard to the rejection over Jacobsen and Greene in view of Lanphere.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Michael G. Hartley/

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